

510(k) SUMMARY**Anspach Knotless Suture Anchor**

A suture Anchor per CFR 21, Part 888.3040, is a smooth or threaded metallic bone fixation fastener and is a Class II device.

The Anspach anchor is a design modification of the existing Anspach Suture Anchor that permits soft tissue attachment to bone but does so in a manner that eliminates the need for the surgeon to have to tie sutures to the anchor.

This device can reduce surgical procedure time, surgeon frustration and fatigue associated with arthroscopic knot tying.

The device is indicated for use in reattachment (fixation) of soft tissues to bone in applications including the pubis, ischium, ileum, humerus, scapula, radius, ulna, femur, tibia, fibula, patella and bones of the hand and foot. It is specifically not intended for use in the spine or for repair of the anterior or posterior cruciate ligaments.

The Anspach Knotless Anchor is indicated for use with specific brands and types of suture materials, which include the following:

Arthrotek:	"MaxBraid"
Smith & Nephew:	"UltraBraid"
Opus Medical:	"Magnum Wire"
Linvatec:	"Herculine"

Suture materials identified as "Braided # 2 polyester" and Arthrex # 2 "Fiberwire" are not recommended for use with the Anspach Arthroscopic Knotless Anchor.

The Anspach Knotless Anchor is constructed of the same materials under the same manufacturing process controls as existing devices. It introduces no new or modified indications for use, risks, hazards, safety or effectiveness issues, and may help reduce surgical time which can be a significant benefit to the patient. Testing has confirmed the Knotless Anchor to be as effective (or more so) in placement and performance as other marketed devices, including the predicate Anspach device(s).

Packaging, labeling, handling and storage conditions are consistent with current designs and accessory tools used in placement of the anchor are essentially the same as existing devices. There are no changes to cleaning, storage processes from existing accessory devices.

The Anspach Knotless Anchor is distributed pre-sterilized to an SAL of 10^6 . Accessory surgical tools are packaged clean, non-sterile and distributed separate from the anchor device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 5 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

William G. Conety
Director, Regulatory Affairs and Quality Assurance
The Anspach Effort, Inc.
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K052572

Trade/Device Name: Anspach Knotless Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: September 16, 2005
Received: September 19, 2005

Dear Mr. Conety:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


for Mark N. Melkerson

Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K052572

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Device Name: Knotless Anchor

INDICATIONS FOR USE:

The Anspach Arthroscopic Knotless Anchor is indicated for use in reattachment (fixation) of soft tissues to bone in applications including the pubis, ischium, ileum, humerus, scapula, radius, ulna, femur, tibia, fibula, patella and bones of the hand and foot. The Anspach Arthroscopic Knotless Anchor is specifically not intended for use in the spine or for repair of the anterior or posterior cruciate ligaments.

The Anspach Arthroscopic Knotless Anchor is used with specific brands and types of suture materials including: Arthrotek "MaxBraid"; Smith & Nephew "UltraBraid"; Opus Medical "Magnum Wire"; and Linvetec "Herculine. Suture materials identified as "Braided # 2 polyester" and Arthrex # 2 "Fiberwire" are not recommended for use with The Anspach Arthroscopic Knotless Anchor.


Prescription Use: √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use: _____
(21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED**

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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